

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

JODI ROUVIERE, Individually and  
ANDRE ROUVIERE, her husband, Individually,

Plaintiff,

v.

DEPUY ORTHOPAEDICS, INC.  
DEPUY PRODUCTS, INC.,  
DEPUY INTERNATIONAL, LIMITED,  
JOHNSON & JOHNSON, INC.,  
and JOHNSON & JOHNSON SERVICES, INC.  
and STRYKER CORPORATION,  
STRYKER SALES CORPORATION, and  
HOWMEDICA OSTEONICS CORPORATION  
d/b/a STRYKER ORTHOPAEDICS,

Defendants.

Case No.: 1:18-cv-04814-AJN

**DEFENDANT HOWMEDICA  
OSTEONICS CORP.'S ANSWER TO  
AMENDED COMPLAINT AND  
AFFIRMATIVE DEFENSES**

Defendant Howmedica Osteonics Corp. (incorrectly named as “Howmedica Osteonics Corporation d/b/a Stryker Orthopaedics”) (“HOC”), by and through its counsel, Gibbons P.C., as and for its Answer to Plaintiffs’ Amended Complaint (“Complaint”), states as follows:

**I. INTRODUCTION**

1. HOC admits that Plaintiffs purport to bring this action as indicated in the Complaint, but denies that there is any legal or factual basis for such relief. HOC denies the remaining allegations contained in Paragraph “1” of the Complaint.

2. The allegations contained in Paragraph “2” of the Complaint relate to a party other than the answering party. Accordingly, HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “2” of the Complaint, and further states that HOC does not design, manufacture, market or sell the Summit Tapered Hip System.

3. The allegations contained in Paragraph “3” of the Complaint relate to a party other than the answering party. Accordingly, HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “3” of the Complaint, and further states that HOC does not design, manufacture, market or sell the Summit Tapered Hip System.

4. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “4” of the Complaint pertaining to the medical device implanted in and explanted from Plaintiff Jodi Rouviere, and leaves Plaintiffs to their proofs. HOC further states that it does not design, manufacture, market or sell the Summit Tapered Hip System.

5. The allegations contained in Paragraph “5” of the Complaint set forth conclusions of law to which no response is required. To the extent a response is required, HOC admits only that this case is currently venued in the Southern District of New York.

6. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “6” of the Complaint, and leaves Plaintiffs to their proofs. To the extent the allegations contained in Paragraph “6” of the Complaint are intended to impute liability to HOC, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “6” of the Complaint.

7. Responding to Paragraph “7” of the Complaint, HOC admits that it designs, manufactures, markets and sells the Restoration® ADM/MDM™ X3® System. HOC denies the remaining allegations contained in Paragraph “7” of the Complaint.<sup>1</sup>

8. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “8” of the Complaint regarding identification of

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<sup>1</sup> HOC notes that Stryker Corporation and Stryker Sales Corporation were incorrectly named as defendants, and all claims against them have been voluntarily dismissed by Plaintiffs.

the medical device implanted in Plaintiff Jodi Rouviere, and leaves Plaintiffs to their proofs. HOC denies the remaining allegations contained in Paragraph “8” of the Complaint.

9. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “9” of the Complaint regarding identification of the medical device implanted in and explanted from Plaintiff Jodi Rouviere, and leaves Plaintiffs to their proofs. To the extent these allegations are intended to impute liability to HOC, they are denied. The remainder of Paragraph “9” of the Complaint consists of Plaintiffs’ use of a definition throughout the Complaint, to which no response is required.

10. The allegations contained in Paragraph “10” of the Complaint set forth conclusions of law to which no response is required. To the extent a response is required, HOC admits only that this case is currently venued in the Southern District of New York.

11. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “11” of the Complaint, and leaves Plaintiffs to their proofs. To the extent the allegations are intended to impute liability to HOC, they are denied.

12. The allegations contained in Paragraph “12” of the Complaint set forth conclusions of law to which no response is required. To the extent a response is required, HOC denies the allegations contained in Paragraph “12” of the Complaint.

## **II. THE PARTIES**

13. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “13” of the Complaint, and leaves Plaintiffs to their proofs.

14. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “14” of the Complaint, and leaves Plaintiffs to their proofs.

15. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “15” of the Complaint, and leaves Plaintiffs to their proofs.

16. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “16” of the Complaint, and leaves Plaintiffs to their proofs.

17. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “17” of the Complaint, and leaves Plaintiffs to their proofs.

18. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “18” of the Complaint, and leaves Plaintiffs to their proofs.

19. The allegations contained in Paragraph “19” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “19” of the Complaint.

20. The allegations contained in Paragraph “20” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “20” of the Complaint.

21. The allegations contained in Paragraph “21” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “21” of the Complaint.

22. The allegations contained in Paragraph “22” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “22” of the Complaint.

23. The allegations contained in Paragraph “23” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “23” of the Complaint.

24. The allegations contained in Paragraph “24” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “24” of the Complaint.

25. The allegations contained in Paragraph “25” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “25” of the Complaint.

26. The allegations contained in Paragraph “26” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “26” of the Complaint.

27. The allegations contained in Paragraph “27” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “27” of the Complaint.

28. The allegations contained in Paragraph “28” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “28” of the Complaint.

29. The allegations contained in Paragraph “29” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “29” of the Complaint.

30. The allegations contained in Paragraph “30” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “30” of the Complaint.

31. The allegations contained in Paragraph “31” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “31” of the Complaint.

32. HOC denies the allegations contained in Paragraph “32” of the Complaint to the extent they are directed to HOC, and otherwise denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “32” of the Complaint.

33. The allegations contained in Paragraph “33” of the Complaint set forth conclusions of law to which no response is required. To the extent a response is required, HOC denies the allegations contained in Paragraph “33” of the Complaint to the extent they are directed to HOC, and otherwise denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “33” of the Complaint.

34. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “34” of the Complaint regarding Plaintiff’s receipt of the Summit Tapered Hip System, and leaves Plaintiffs to their proofs. The remaining allegations contained in Paragraph “34” of the Complaint set forth conclusions of law to which no response is required. To the extent a response is required, HOC denies the allegations contained in Paragraph “34” of the Complaint to the extent they are directed to HOC, and states that it does not design, manufacture, market or sell the Summit Tapered Hip System.

35. HOC denies the allegations contained in Paragraph “35” of the Complaint to the extent they are directed to HOC, and states that it does not design, manufacture, market or sell the Summit Tapered Hip System.

36. The allegations contained in Paragraph “36” of the Complaint relate to an entity that has been dismissed from the case, and thus no response is required. To the extent a response is required, HOC admits that Stryker Corporation is a Michigan corporation with its principal

place of business located in Kalamazoo, Michigan. HOC denies the remaining allegations contained in Paragraph “36” of the Complaint.

37. The allegations contained in Paragraph “37” of the Complaint relate to an entity that has been dismissed from the case, and thus no response is required. To the extent a response is required, HOC admits only that Stryker Corporation is a Michigan corporation with its principal place of business located in Kalamazoo, Michigan. HOC denies the remaining allegations contained in Paragraph “37” of the Complaint.

38. The allegations contained in Paragraph “38” of the Complaint relate to an entity that has been dismissed from the case, and thus no response is required. To the extent a response is required, HOC admits only that Stryker Corporation has done business in New York. HOC denies the remaining allegations contained in Paragraph “38” of the Complaint.

39. The allegations contained in Paragraph “39” of the Complaint relate to an entity that has been dismissed from the case, and thus no response is required. To the extent a response is required, HOC denies the allegations contained in Paragraph “39” of the Complaint.

40. The allegations contained in Paragraph “40” of the Complaint relate to an entity that has been dismissed from the case, and thus no response is required. To the extent a response is required, HOC admits that Stryker Corporation has done business in New York. HOC denies the remaining allegations contained in Paragraph “40” of the Complaint.

41. The allegations contained in Paragraph “41” of the Complaint relate to an entity that has been dismissed from the case, and thus no response is required. To the extent a response is required, HOC admits that Stryker Corporation has done business in New York. HOC denies the remaining allegations contained in Paragraph “41” of the Complaint.

42. The allegations contained in Paragraph “42” of the Complaint relate to an entity that has been dismissed from the case, and thus no response is required. To the extent a response is required, HOC denies the allegations contained in Paragraph “42” of the Complaint.

43. The allegations contained in Paragraph “43” of the Complaint relate to an entity that has been dismissed from the case, and thus no response is required. To the extent a response is required, HOC admits that Stryker Sales Corporation is a Michigan corporation with its principal place of business located in Kalamazoo, Michigan. HOC denies the remaining allegations contained in Paragraph “43” of the Complaint.

44. The allegations contained in Paragraph “44” of the Complaint relate to an entity that has been dismissed from the case, and thus no response is required. To the extent a response is required, HOC admits that Stryker Sales Corporation is a Michigan corporation with its principal place of business located in Kalamazoo, Michigan. HOC denies the remaining allegations contained in Paragraph “44” of the Complaint.

45. The allegations contained in Paragraph “45” of the Complaint relate to an entity that has been dismissed from the case, and thus no response is required. To the extent a response is required, HOC admits that Stryker Sales Corporation has done business in New York. HOC denies the remaining allegations contained in Paragraph “45” of the Complaint.

46. The allegations contained in Paragraph “46” of the Complaint relate to an entity that has been dismissed from the case, and thus no response is required. To the extent a response is required, HOC admits that Stryker Sales Corporation has done business in New York. HOC denies the remaining allegations contained in Paragraph “46” of the Complaint.

47. The allegations contained in Paragraph “47” of the Complaint relate to an entity that has been dismissed from the case, and thus no response is required. To the extent a response is required, HOC denies the allegations contained in Paragraph “47” of the Complaint.

48. The allegations contained in Paragraph “48” of the Complaint relate to an entity that has been dismissed from the case, and thus no response is required. To the extent a response is required, HOC admits that Stryker Sales Corporation has done business in New York. HOC denies the remaining allegations contained in Paragraph “48” of the Complaint.



49. The allegations contained in Paragraph “49” of the Complaint relate to an entity that has been dismissed from the case, and thus no response is required. To the extent a response is required, HOC admits that Stryker Sales Corporation has done business in New York. HOC denies the remaining allegations contained in Paragraph “49” of the Complaint.

50. The allegations contained in Paragraph “50” of the Complaint relate to an entity that has been dismissed from the case, and thus no response is required. To the extent a response is required, HOC denies the allegations contained in Paragraph “50” of the Complaint.

51. Responding to Paragraph “51” of the Complaint, HOC admits that it is a New Jersey corporation with its principal place of business located at 325 Corporate Drive, Mahwah, New Jersey. HOC denies the remaining allegations contained in Paragraph “51” of the Complaint.

52. Responding to Paragraph “52” of the Complaint, HOC admits that it is a New Jersey corporation with its principal place of business located at 325 Corporate Drive, Mahwah, New Jersey. HOC denies the remaining allegations contained in Paragraph “52” of the Complaint.

53. Responding to Paragraph “53” of the Complaint, HOC admits that it has done business in New York. HOC denies the remaining allegations contained in Paragraph “53” of the Complaint.

54. HOC denies the allegations contained in Paragraph “54” of the Complaint to the extent they are directed to HOC or relate to the Restoration® ADM/MDM™ X3® System.

55. Responding to Paragraph “55” of the Complaint, HOC admits that it has done business in New York. HOC denies the remaining allegations contained in Paragraph “55” of the Complaint.

56. Responding to Paragraph “56” of the Complaint, HOC admits that it has done business in New York. HOC denies the remaining allegations contained in Paragraph “56” of the Complaint.

57. HOC denies the allegations contained in Paragraph “57” of the Complaint.

58. HOC denies the allegations contained in Paragraph “58” of the Complaint.

59. Responding to Paragraph “59” of the Complaint, HOC admits that it has done business in New York. HOC denies the remaining allegations contained in Paragraph “59” of the Complaint.

60. Responding to Paragraph “60” of the Complaint, HOC admits that it has done business in New York. HOC denies the remaining allegations contained in Paragraph “60” of the Complaint.

61. HOC denies the allegations contained in Paragraph “61” of the Complaint.

### **III. JURISDICTION AND VENUE**

62. The allegations contained in Paragraph “62” of the Complaint set forth conclusions of law to which no response is required. To the extent a response is required, HOC admits that the parties are of diverse citizenship and that Plaintiffs claim that the amount in controversy exceeds \$75,000.00 exclusive of interest and costs.

63. The allegations contained in Paragraph “63” of the Complaint set forth conclusions of law to which no response is required.

64. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “64” of the Complaint, and leaves Plaintiffs to their proofs.

65. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “65” of the Complaint, and leaves Plaintiffs to their proofs.

66. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “66” of the Complaint, and leaves Plaintiffs to their proofs.

67. Responding to Paragraph “67” of the Complaint, HOC admits that it is a New Jersey corporation with its principal place of business located at 325 Corporate Drive, Mahwah, New Jersey. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph “67” of the Complaint, and leaves Plaintiffs to their proofs.

68. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “68” of the Complaint, and leaves Plaintiffs to their proofs.

69. The allegations contained in Paragraph “69” of the Complaint set forth conclusions of law to which no response is required. To the extent a response is required, HOC denies the allegations contained in Paragraph “69” of the Complaint.

70. The allegations contained in Paragraph “70” of the Complaint relate to a party other than the answering party. To the extent the allegations contained in Paragraph “70” of the Complaint are intended to impute liability to HOC, HOC denies the allegations and states that it does not design, manufacture, market or sell the Summit Tapered Hip System.

71. Responding to Paragraph “71” of the Complaint, HOC admits that it has done business in New York. HOC further admits that it designs, manufactures, markets and sells the Restoration® ADM/MDM™ X3® System. HOC denies the remaining allegations contained in Paragraph “71” of the Complaint.

72. HOC denies the allegations contained in Paragraph “72” of the Complaint.

73. HOC denies the allegations contained in Paragraph “73” of the Complaint.

#### **IV. FACTUAL BACKGROUND**

74. The allegations contained in Paragraph “74” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “74” of the Complaint.

75. HOC denies the allegations contained in Paragraph “75” of the Complaint.

76. The allegations contained in Paragraph “76” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “76” of the Complaint.

77. The allegations contained in Paragraph “77” of the Complaint relate to a party other than the answering party. To the extent the allegations contained in Paragraph “77” of the Complaint are intended to impute liability to HOC, HOC denies the allegations and states that it does not design, manufacture, market or sell the Summit Tapered Hip System.

78. The allegations contained in Paragraph “78” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “78” of the Complaint.

79. The allegations contained in Paragraph “79” of the Complaint set forth conclusions of law to which no response is required. To the extent a response is required, HOC denies the allegations contained in Paragraph “79” of the Complaint.

80. HOC denies the allegations contained in Paragraph “80” of the Complaint.

81. HOC denies the allegations contained in Paragraph “81” of the Complaint.

**RESPONSE TO ALLEGATIONS REGARDING  
THE SUMMIT TAPERED HIP SYSTEM**

82. The allegations contained in Paragraph “82” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraph “82” of the Complaint.

83. Responding to Paragraph “83” of the Complaint,, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “83” of the Complaint pertaining to the description of the Summit Tapered Hip System, and leaves Plaintiffs to their proofs. HOC further denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “83” of the Complaint pertaining to Plaintiff Jodi Rouviere’s medical device, and leaves Plaintiffs to their proofs. HOC denies the remaining allegations contained in Paragraph “83” of the Complaint.

84. Responding to Paragraph “84” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “84” of the Complaint to the extent they are directed to HOC.

85. Responding to Paragraph “85” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “85” of the Complaint to the extent they are directed to HOC.

86. Responding to Paragraph “86” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “86” of the Complaint to the extent they are directed to HOC.

87. Responding to Paragraph “87” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies knowledge or

information sufficient to form a belief as to the truth of the allegations contained in Paragraph “87” of the Complaint.

88. Responding to Paragraph “88” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “88” of the Complaint to the extent they are directed to HOC.

89. Responding to Paragraph “89” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “89” of the Complaint to the extent they are directed to HOC.

90. Responding to Paragraph “90” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “90” of the Complaint to the extent they are directed to HOC.

91. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “91” of the Complaint pertaining Plaintiff Jodi Rouviere’s receipt of a medical device, and leaves Plaintiffs to their proofs. HOC denies the remaining allegations contained in Paragraph “91” of the Complaint.

92. Responding to Paragraph “92” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System. HOC further denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “92” of the Complaint, and leaves Plaintiffs to their proofs.

**RESPONSE TO ALLEGATIONS THAT  
DEFENDANTS DEPUY CLEARED SUMMIT  
TAPERED HIP SYSTEM AS A CLASS II DEVICE  
WITHOUT PRE-MARKET APPROVAL**

93. Responding to Paragraph “93” of the Complaint, HOC admits that the Medical Device Amendments of 1976 (“MDA”), 21 U.S.C. § 360k, to the Federal Food, Drug and Cosmetics Act (“FDCA”) were enacted in 1976. HOC denies the remaining allegations

contained in Paragraph “93” of the Complaint, as characterized by Plaintiffs.

94. HOC denies the allegations contained in Paragraph “94” of the Complaint, as characterized by Plaintiffs.

95. Responding to Paragraph “95” of the Complaint, HOC responds that the website, statutes, regulation, and opinion referenced in Paragraph “95” of the Complaint speak for themselves. To the extent the allegations contained in Paragraph “95” of the Complaint are intended to impute liability to HOC, HOC denies the allegations, as characterized by Plaintiffs.

96. HOC denies the allegations contained in Paragraph “96” of the Complaint.

97. Responding to Paragraph “97” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “97” of the Complaint to the extent they are directed to HOC.

98. Responding to Paragraph “98” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “98” of the Complaint to the extent they are directed to HOC. HOC further states that the opinion referenced in Paragraph “98” of the Complaint speaks for itself.

99. Responding to Paragraph “99” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “99” of the Complaint to the extent they are directed to HOC.

100. Responding to Paragraph “100” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System. HOC further denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “100” of the Complaint.

101. Responding to Paragraph “101” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “101” of the Complaint to the extent they are directed to HOC.

102. Responding to Paragraph “102” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “102” of the Complaint to the extent they are directed to HOC.

103. Responding to Paragraph “103” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “103” of the Complaint to the extent they are directed to HOC.

104. Responding to Paragraph “104” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “104” of the Complaint to the extent they are directed to HOC.

105. HOC denies the allegations contained in Paragraph “105” of the Complaint.

106. Responding to Paragraph “106” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “106” of the Complaint to the extent they are directed to HOC.

107. Responding to Paragraph “107” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “107” of the Complaint to the extent they are directed to HOC.

108. Responding to Paragraph “108” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph “108” of the Complaint.

109. Responding to Paragraph “109” of the Complaint, HOC responds that the unspecified journal article referenced in Paragraph “109” of the Complaint speaks for itself. To the extent the allegations contained in Paragraph “109” of the Complaint are intended to impute liability to HOC, HOC denies the allegations.



110. Responding to Paragraph “110” of the Complaint, HOC responds that the journal article referenced in Paragraph “110” of the Complaint speaks for itself. To the extent the allegations contained in Paragraph “110” of the Complaint are intended to impute liability to HOC, HOC denies the allegations.

111. Responding to Paragraph “111” of the Complaint, HOC responds that the journal article referenced in Paragraph “111” of the Complaint speaks for itself. To the extent the allegations contained in Paragraph “111” of the Complaint are intended to impute liability to HOC, HOC denies the allegations.

112. Responding to Paragraph “112” of the Complaint, HOC responds that the journal article referenced in Paragraph “112” of the Complaint speaks for itself. To the extent the allegations contained in Paragraph “112” of the Complaint are intended to impute liability to HOC, HOC denies the allegations.

113. HOC denies the allegations contained in Paragraph “113” of the Complaint.

114. Responding to Paragraph “114” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “114” of the Complaint to the extent they are directed to HOC.

**RESPONSE TO ALLEGATIONS THAT  
DEFENDANTS STRYKER CLEARED “THE MDM®X3®”  
ADM/MDM SYSTEM, “THE RESTORATION®”  
ADM/MDM SYSTEM AS A CLASS II DEVICE  
WITHOUT PRE MARKET APPROVAL**

115. Responding to Paragraph “115” of the Complaint, HOC admits that the MDA, 21 U.S.C. § 360k, to the FDCA was enacted in 1976. HOC denies the remaining allegations contained in Paragraph “115” of the Complaint, as characterized by Plaintiffs.

116. HOC denies the allegations contained in Paragraph “116” of the Complaint, as characterized by Plaintiffs.

117. Responding to Paragraph “117” of the Complaint, HOC responds that the website, statutes, regulation, and opinion referenced in Paragraph “117” of the Complaint speak for themselves. To the extent the allegations contained in Paragraph “117” of the Complaint are intended to impute liability to HOC, HOC denies the allegations, as characterized by Plaintiffs.

118. HOC denies the allegations contained in Paragraph “118” of the Complaint.

119. HOC denies the allegations contained in Paragraph “119” of the Complaint, and, further answering, states that the Restoration® ADM/MDM™ X3® System underwent the appropriate regulatory review required by law.

120. Responding to Paragraph “120” of the Complaint, HOC responds that the allegation stated in Paragraph “120” of the Complaint speaks for itself, and denies the allegation to the extent it is intended to impute liability to HOC. HOC denies the remaining allegations contained in Paragraph “120” of the Complaint, including, but not limited to, any insinuation that the Restoration® ADM/MDM™ X3® System did not receive appropriate FDA clearance. Further answering, HOC states that the Restoration® ADM/MDM™ X3® System underwent the appropriate regulatory review required by law.

121. HOC denies the allegations contained in Paragraph “121” of the Complaint, and, further answering, states that the Restoration® ADM/MDM™ X3® System underwent the appropriate regulatory review required by law.

122. Responding to Paragraph “122” of the Complaint, HOC denies any insinuation that the Restoration® ADM/MDM™ X3® System was required to or should have undergone the Premarket Approval process and therefore denies the allegations contained in Paragraph 122 of the Complaint. Further answering, HOC states that the Restoration® ADM/MDM™ X3® System underwent the appropriate regulatory review required by law.

123. Responding to Paragraph “123” of the Complaint, HOC denies any insinuation that the Restoration® ADM/MDM™ X3® System was required to or should have undergone the

Premarket Approval process, and, therefore, denies the allegations contained in Paragraph 123 of the Complaint. Further answering, HOC states that the Restoration® ADM/MDM™ X3® System underwent the appropriate regulatory review required by law.

124. HOC denies the allegations contained in Paragraph “124” of the Complaint. HOC further states that it does not design, manufacture, market or sell the Summit Tapered Hip System.

125. HOC denies the allegations contained in Paragraph “125” of the Complaint.

126. HOC denies the allegations contained in Paragraph “126” of the Complaint.

127. HOC denies the allegations contained in Paragraph “127” of the Complaint.

128. HOC denies the allegations contained in Paragraph “128” of the Complaint.

129. HOC denies the allegations contained in Paragraph “129” of the Complaint.

**RESPONSE TO ALLEGATIONS REGARDING  
THE FAILURE OF PLAINTIFF’S SUMMIT DEVICE**

130. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “130” of the Complaint, and leaves Plaintiffs to their proofs. To the extent the allegations contained in Paragraph “130” seek to impute liability to HOC, they are denied.

131. Responding to Paragraph “131” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System. HOC further denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “131” of the Complaint. To the extent the allegations contained in Paragraph “131” seek to impute liability to HOC, they are denied.

132. Responding to Paragraph “132” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System. HOC further denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations

contained in Paragraph “132” of the Complaint. To the extent the allegations contained in Paragraph “132” seek to impute liability to HOC, they are denied.

133. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “133” of the Complaint. To the extent the allegations contained in Paragraph “133” seek to impute liability to HOC, they are denied.

134. Responding to Paragraph “134” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System. HOC further denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “134” of the Complaint. To the extent the allegations contained in Paragraph “134” seek to impute liability to HOC, they are denied.

135. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “135” of the Complaint. To the extent the allegations contained in Paragraph “135” seek to impute liability to HOC, they are denied.

136. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “136” of the Complaint. To the extent the allegations contained in Paragraph “136” seek to impute liability to HOC, they are denied.

137. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “137” of the Complaint. To the extent the allegations contained in Paragraph “137” seek to impute liability to HOC, they are denied.

138. Responding to Paragraph “138” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and, further answering, HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “138” of the Complaint. To the extent the allegations contained in Paragraph “138” seek to impute liability to HOC, they are denied.

139. Responding to Paragraph “139” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and, further answering, HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “139” of the Complaint. To the extent the allegations contained in Paragraph “139” seek to impute liability to HOC, they are denied.

140. Responding to Paragraph “140” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and, further answering, HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “140” of the Complaint. To the extent the allegations contained in Paragraph “140” seek to impute liability to HOC, they are denied.

141. Responding to Paragraph “141” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and, further answering, HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “141” of the Complaint. To the extent the allegations contained in Paragraph “141” seek to impute liability to HOC, they are denied.

142. Responding to Paragraph “142” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and, further answering, HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “142” of the Complaint. To the extent the allegations contained in Paragraph “142” seek to impute liability to HOC, they are denied.

143. HOC denies the allegations contained in Paragraph “143” of the Complaint.

144. Responding to Paragraph “144” of the Complaint, HOC admits that the Agency for Toxic Substances & Disease Registry issues toxicological profile information for various substances which speak for themselves. HOC denies any remaining allegations.

145. HOC denies the allegations contained in Paragraph “145” of the Complaint.

146. HOC denies the allegations contained in Paragraph “146” of the Complaint.

147. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “147” of the Complaint.

148. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “148” of the Complaint.

149. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “149” of the Complaint.

150. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “150” of the Complaint.

151. HOC denies the allegations contained in Paragraph “151” of the Complaint.

152. HOC denies the allegations contained in Paragraph “152” of the Complaint.

153. HOC denies the allegations contained in Paragraph “153” of the Complaint.

154. HOC denies the allegations contained in Paragraph “154” of the Complaint.

155. HOC denies the allegations contained in Paragraph “155” of the Complaint.

156. HOC denies the allegations contained in Paragraph “156” of the Complaint.

157. HOC denies the allegations contained in Paragraph “157” of the Complaint.

158. HOC denies the allegations contained in Paragraph “158” of the Complaint.

159. HOC denies the allegations contained in Paragraph “159” of the Complaint.

160. HOC denies the allegations contained in Paragraph “160” of the Complaint.

161. HOC denies the allegations contained in Paragraph “161” of the Complaint.

162. Responding to Paragraph “162” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “162” of the Complaint to the extent they are directed to HOC.

163. HOC denies the allegations contained in Paragraph “163” of the Complaint.

164. Responding to Paragraph “164” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “164” of the Complaint to the extent they are directed to HOC.

165. HOC denies the allegations contained in Paragraph “165” of the Complaint.

166. The allegations contained in Paragraph “166” of the Complaint set forth conclusions of law to which no response is required. To the extent a response is required, HOC denies the allegations contained in Paragraph “166” of the Complaint to the extent they are directed to HOC.

167. Responding to Paragraph “167” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “167” of the Complaint to the extent they are directed to HOC.

168. HOC denies the allegations contained in Paragraph “168” of the Complaint.

169. Responding to Paragraph “169” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “169” of the Complaint to the extent they are directed to HOC.

170. HOC denies the allegations contained in Paragraph “170” of the Complaint.

171. Responding to Paragraph “171” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “171” of the Complaint to the extent they are directed to HOC.

172. HOC denies the allegations contained in Paragraph “172” of the Complaint.

173. Responding to Paragraph “173” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “173” of the Complaint to the extent they are directed to HOC.

174. HOC denies the allegations contained in Paragraph “174” of the Complaint.

175. Responding to Paragraph “175” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “175” of the Complaint to the extent they are directed to HOC.

176. HOC denies the allegations contained in Paragraph “176” of the Complaint.

177. Responding to Paragraph “177” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “177” of the Complaint to the extent they are directed to HOC.

178. HOC denies the allegations contained in Paragraph “178” of the Complaint.

179. Responding to Paragraph “179” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “179” of the Complaint to the extent they are directed to HOC.

180. HOC denies the allegations contained in Paragraph “180” of the Complaint.

181. Responding to Paragraph “181” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “181” of the Complaint to the extent they are directed to HOC.

182. HOC denies the allegations contained in Paragraph “182” of the Complaint.

183. Responding to Paragraph “183” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “183” of the Complaint to the extent they are directed to HOC.

184. HOC denies the allegations contained in Paragraph “184” of the Complaint.

185. Responding to Paragraph “185” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “185” of the Complaint to the extent they are directed to HOC.



186. Responding to Paragraph “186” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “186” of the Complaint to the extent they are directed to HOC.

187. Responding to Paragraph “187” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “187” of the Complaint.

188. Responding to Paragraph “188” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “188” of the Complaint to the extent they are directed to HOC.

189. Responding to Paragraph “189” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “189” of the Complaint to the extent they are directed to HOC.

190. Responding to Paragraph “190” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “190” of the Complaint to the extent they are directed to HOC.

191. Responding to Paragraph “191” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “191” of the Complaint to the extent they are directed to HOC.

192. Responding to Paragraph “192” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “192” of the Complaint to the extent they are directed to HOC.

193. Responding to Paragraph “193” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “193” of the Complaint to the extent they are directed to HOC.

194. Responding to Paragraph “194” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “194” of the Complaint to the extent they are directed to HOC.

195. Responding to Paragraph “195” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “195” of the Complaint to the extent they are directed to HOC.

196. HOC denies the allegations contained in Paragraph “196” of the Complaint.

197. Responding to Paragraph “197” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “197” of the Complaint.

198. Responding to Paragraph “198” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “198” of the Complaint.

199. Responding to Paragraph “199” of the Complaint, HOC responds that the statute, regulations, and opinions referenced in Paragraph “199” of the Complaint speak for themselves. To the extent the allegations contained in Paragraph “199” of the Complaint are intended to impute liability to HOC, HOC denies the allegations, as characterized by Plaintiffs.

200. Responding to Paragraph “200” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “200” of the Complaint to the extent they are directed to HOC.

201. Responding to Paragraph “201” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “201” of the Complaint to the extent they are directed to HOC.

202. Responding to Paragraph “202” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “202” of the Complaint to the extent they are directed to HOC.

203. Responding to Paragraph “203” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “203” of the Complaint to the extent they are directed to HOC.

204. Responding to Paragraph “204” of the Complaint, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraph “204” of the Complaint to the extent they are directed to HOC.

205. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “205” of the Complaint, and leaves Plaintiffs to their proofs. To the extent the allegations contained in Paragraph “205” seek to impute liability to HOC, they are denied.

206. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “206” of the Complaint, and leaves Plaintiffs to their proofs. To the extent the allegations contained in Paragraph “206” seek to impute liability to HOC, they are denied.

207. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “207” of the Complaint, and leaves Plaintiffs to their proofs. To the extent the allegations contained in Paragraph “207” seek to impute liability to HOC, they are denied.

208. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “208” of the Complaint, and leaves Plaintiffs to their proofs. To the extent the allegations contained in Paragraph “208” seek to impute liability to HOC, they are denied.

209. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “209” of the Complaint, and leaves Plaintiffs to their proofs. To the extent the allegations contained in Paragraph “209” seek to impute liability to HOC, they are denied.

210. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “210” of the Complaint, and leaves Plaintiffs to their proofs. To the extent the allegations contained in Paragraph “210” seek to impute liability to HOC, they are denied.

211. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “211” of the Complaint, and leaves Plaintiffs to their proofs. To the extent the allegations contained in Paragraph “211” seek to impute liability to HOC, they are denied.

212. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “212” of the Complaint, and leaves Plaintiffs to their proofs. To the extent the allegations contained in Paragraph “212” seek to impute liability to HOC, they are denied.

213. HOC denies the allegations contained in Paragraph “213” of the Complaint.

214. HOC denies the allegations contained in Paragraph “214” of the Complaint.

215. HOC denies the allegations contained in Paragraph “215” of the Complaint.

216. HOC denies the allegations contained in Paragraph “216” of the Complaint.

217. HOC denies the allegations contained in Paragraph “217” of the Complaint.

218. HOC denies the allegations contained in Paragraph “218” of the Complaint.

219. Responding to Paragraph “219” of the Complaint, HOC admits that the Agency for Toxic Substances & Disease Registry issues toxicological profile information for various substances which speak for themselves. HOC denies any remaining allegations.

220. HOC denies the allegations contained in Paragraph “220” of the Complaint.

221. HOC denies the allegations contained in Paragraph “221” of the Complaint.

222. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “222” of the Complaint.

223. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “223” of the Complaint.

224. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “224” of the Complaint.

225. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “225” of the Complaint.

226. HOC denies the allegations contained in Paragraph “226” of the Complaint.

227. HOC denies the allegations contained in Paragraph “227” of the Complaint.

228. HOC denies the allegations contained in Paragraph “228” of the Complaint.

229. HOC denies the allegations contained in Paragraph “229” of the Complaint.

230. HOC denies the allegations contained in Paragraph “230” of the Complaint.

231. HOC denies the allegations contained in Paragraph “231” of the Complaint.

232. HOC denies the allegations contained in Paragraph “232” of the Complaint.

233. HOC denies the allegations contained in Paragraph “233” of the Complaint.

234. HOC denies the allegations contained in Paragraph “234” of the Complaint.

235. HOC denies the allegations contained in Paragraph “235” of the Complaint.

236. HOC denies the allegations contained in Paragraph “236” of the Complaint.

237. HOC denies the allegations contained in Paragraph “237” of the Complaint.

238. HOC denies the allegations contained in Paragraph “238” of the Complaint.

239. HOC denies the allegations contained in Paragraph “239” of the Complaint.

240. HOC denies the allegations contained in Paragraph “240” of the Complaint.

241. The allegations contained in Paragraph “241” of the Complaint set forth conclusions of law to which no response is required. To the extent a response is required, HOC denies the allegations contained in Paragraph “241” of the Complaint.

242. HOC denies the allegations contained in Paragraph “242” of the Complaint.

243. HOC denies the allegations contained in Paragraph “243” of the Complaint.

244. HOC denies the allegations contained in Paragraph “244” of the Complaint.

245. HOC denies the allegations contained in Paragraph “245” of the Complaint.

246. HOC denies the allegations contained in Paragraph “246” of the Complaint.

247. HOC denies the allegations contained in Paragraph “247” of the Complaint.

248. HOC denies the allegations contained in Paragraph “248” of the Complaint.

249. HOC denies the allegations contained in Paragraph “249” of the Complaint.

250. HOC denies the allegations contained in Paragraph “250” of the Complaint.

251. HOC denies the allegations contained in Paragraph “251” of the Complaint.

252. HOC denies the allegations contained in Paragraph “252” of the Complaint.

253. HOC denies the allegations contained in Paragraph “253” of the Complaint.

254. HOC denies the allegations contained in Paragraph “254” of the Complaint.

255. HOC denies the allegations contained in Paragraph “255” of the Complaint.

256. HOC denies the allegations contained in Paragraph “256” of the Complaint.

257. HOC denies the allegations contained in Paragraph “257” of the Complaint.

258. HOC denies the allegations contained in Paragraph “258” of the Complaint.

259. HOC denies the allegations contained in Paragraph “259” of the Complaint.

260. HOC denies the allegations contained in Paragraph “260” of the Complaint.

261. HOC denies the allegations contained in Paragraph “261” of the Complaint.

262. HOC denies the allegations contained in Paragraph “262” of the Complaint.

263. HOC denies the allegations contained in Paragraph “263” of the Complaint.

264. HOC denies the allegations contained in Paragraph “264” of the Complaint.

265. HOC denies the allegations contained in Paragraph “265” of the Complaint.

266. HOC denies the allegations contained in Paragraph “266” of the Complaint.

267. HOC denies the allegations contained in Paragraph “267” of the Complaint.

268. HOC denies the allegations contained in Paragraph “268” of the Complaint.

269. HOC denies the allegations contained in Paragraph “269” of the Complaint.

270. HOC denies the allegations contained in Paragraph “270” of the Complaint.

271. HOC denies the allegations contained in Paragraph “271” of the Complaint.

272. HOC denies the allegations contained in Paragraph “272” of the Complaint.

273. Responding to Paragraph “273” of the Complaint, HOC responds that the statute, regulations, and opinions referenced in Paragraph “273” of the Complaint speak for themselves. To the extent the allegations contained in Paragraph “273” of the Complaint are intended to impute liability to HOC, HOC denies the allegations, as characterized by Plaintiffs.

274. HOC denies the allegations contained in Paragraph “274” of the Complaint.

275. HOC denies the allegations contained in Paragraph “275” of the Complaint.

276. HOC denies the allegations contained in Paragraph “276” of the Complaint.

277. HOC denies the allegations contained in Paragraph “277” of the Complaint.

278. Responding to Paragraph “278” of the Complaint, HOC admits that it designs, manufactures, markets and sells the Restoration® ADM/MDM™ X3® System. HOC denies the remaining allegations contained in Paragraph “278” of the Complaint.

**RESPONSE TO FIRST CAUSE OF ACTION AS AGAINST THE DEFENDANTS  
DEPUY (NEGLIGENCE AND NEGLIGENCE PER SE)**

The allegations contained in Paragraphs “279” through “290” (including subparts) of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraphs “279” through “290” (including subparts) of the Complaint. To the extent the allegations contained in Paragraphs “279” through “290” (including subparts) of the Complaint are intended to impute liability to HOC, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraphs “279” through “290” (including subparts) of the Complaint.

**RESPONSE TO SECOND CAUSE OF ACTION AS AGAINST THE DEPUY  
DEFENDANTS (STRICT PRODUCTS LIABILITY)**

The allegations contained in Paragraphs “291” through “315” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraphs “291” through “315” of the Complaint. To the extent the allegations contained in Paragraphs “291” through “315” of the Complaint are intended to impute liability to HOC, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraphs “291” through “315” of the Complaint.



**RESPONSE TO THIRD CAUSE OF ACTION AS AGAINST THE DEPUY  
DEFENDANTS (BREACH OF EXPRESS WARRANTY)**

The allegations contained in Paragraphs “316” through “326” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraphs “316” through “326” of the Complaint. To the extent the allegations contained in Paragraphs “316” through “326” of the Complaint are intended to impute liability to HOC, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraphs “316” through “326” of the Complaint.

**RESPONSE TO FOURTH CAUSE OF ACTION AS AGAINST THE DEPUY  
DEFENDANTS (BREACH OF IMPLIED WARRANTIES)**

The allegations contained in Paragraphs “327” through “337” of the Complaint relate to a party other than the answering party. Accordingly, HOC does not respond to the allegations contained in Paragraphs “327” through “337” of the Complaint. To the extent the allegations contained in Paragraphs “327” through “337” of the Complaint are intended to impute liability to HOC, HOC states that it does not design, manufacture, market or sell the Summit Tapered Hip System, and denies the allegations contained in Paragraphs “327” through “337” of the Complaint.

**RESPONSE TO FIFTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS  
STRYKER (NEGLIGENCE AND NEGLIGENCE PER SE)**

338. HOC repeats each and every response to the allegations set forth in Paragraphs “1” through “337” of the Complaint as if set forth at length herein.

339. The allegations contained in Paragraph “339” of the Complaint set forth conclusions of law to which no response is required. To the extent a response is required, HOC denies the allegations contained in Paragraph “339” of the Complaint.

340. HOC denies the allegations contained in Paragraph “340” of the Complaint.

341. HOC denies the allegations contained in Paragraph “341” (including subparts) of the Complaint.

342. HOC denies the allegations contained in Paragraph “342” of the Complaint.

343. HOC denies the allegations contained in Paragraph “343” of the Complaint.

344. HOC denies the allegations contained in Paragraph “344” (including subparts) of the Complaint.

345. HOC denies the allegations contained in Paragraph “345” of the Complaint.

346. HOC denies the allegations contained in Paragraph “346” of the Complaint.

347. HOC denies the allegations contained in Paragraph “347” of the Complaint.

348. HOC denies the allegations contained in Paragraph “348” of the Complaint.

349. HOC denies the allegations contained in Paragraph “349” of the Complaint.

**WHEREFORE**, HOC demands judgment in its favor and against Plaintiffs, dismissing the Fifth Cause of Action of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

**RESPONSE TO SIXTH CAUSE OF ACTION AS AGAINST THE STRYKER  
DEFENDANTS (STRICT PRODUCTS LIABILITY)**

350. HOC repeats each and every response to the allegations set forth in Paragraphs “1” through “349” of the Complaint as if set forth at length herein.

351. Responding to Paragraph “351” of the Complaint, HOC admits that it designs, manufactures, markets and sells the Restoration® ADM/MDM™ X3® System. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “351” of the Complaint pertaining to the medical device received by Plaintiff Jodi Rouviere, and leaves Plaintiffs to their proofs. HOC denies the remaining allegations contained in Paragraph “351” of the Complaint.

352. HOC denies the allegations contained in Paragraph “352” of the Complaint.

353. HOC denies the allegations contained in Paragraph “353” of the Complaint.

354. HOC denies the allegations contained in Paragraph “354” of the Complaint.

355. HOC denies the allegations contained in Paragraph “355” of the Complaint.

356. HOC denies the allegations contained in Paragraph “356” of the Complaint.

357. HOC denies the allegations contained in Paragraph “357” of the Complaint.

358. HOC denies the allegations contained in Paragraph “358” of the Complaint.

359. The allegations contained in Paragraph “359” of the Complaint set forth conclusions of law to which no response is required. To the extent a response is required, HOC denies the allegations contained in Paragraph “359” of the Complaint.

360. HOC denies the allegations contained in Paragraph “360” of the Complaint.

361. HOC denies the allegations contained in Paragraph “361” of the Complaint.

362. HOC denies the allegations contained in Paragraph “362” of the Complaint.

363. HOC denies the allegations contained in Paragraph “363” of the Complaint.

364. HOC denies the allegations contained in Paragraph “364” of the Complaint.

365. HOC denies the allegations contained in Paragraph “365” of the Complaint.

366. HOC denies the allegations contained in Paragraph “366” of the Complaint.

367. HOC denies the allegations contained in Paragraph “367” of the Complaint.

368. HOC denies the allegations contained in Paragraph “368” of the Complaint.

369. HOC denies the allegations contained in Paragraph “369” of the Complaint.

370. HOC denies the allegations contained in Paragraph “370” of the Complaint.

371. HOC denies the allegations contained in Paragraph “371” of the Complaint.

372. HOC denies the allegations contained in Paragraph “372” of the Complaint.

373. HOC denies the allegations contained in Paragraph “373” of the Complaint.

**WHEREFORE**, HOC demands judgment in its favor and against Plaintiffs, dismissing the Sixth Cause of Action of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

**RESPONSE TO SEVENTH CAUSE OF ACTION AS AGAINST THE STRYKER  
DEFENDANTS (BREACH OF EXPRESS WARRANTY)**

374. HOC repeats each and every response to the allegations set forth in Paragraphs “1” through “373” of the Complaint as if set forth at length herein.

375. HOC denies the allegations contained in Paragraph “375” of the Complaint.

376. HOC denies the allegations contained in Paragraph “376” of the Complaint.

377. HOC denies the allegations contained in Paragraph “377” of the Complaint.

378. HOC denies the allegations contained in Paragraph “378” of the Complaint.

379. HOC denies the allegations contained in Paragraph “379” of the Complaint.

380. HOC denies the allegations contained in Paragraph “380” of the Complaint.

381. HOC denies the allegations contained in Paragraph “381” of the Complaint.

382. HOC denies the allegations contained in Paragraph “382” of the Complaint.

383. HOC denies the allegations contained in Paragraph “383” of the Complaint.

384. HOC denies the allegations contained in Paragraph “384” of the Complaint.

**WHEREFORE**, HOC demands judgment in its favor and against Plaintiffs, dismissing the Seventh Cause of Action of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

**RESPONSE TO EIGHTH CAUSE OF ACTION AS AGAINST THE STRYKER  
DEFENDANTS (BREACH OF IMPLIED WARRANTIES)**

385. HOC repeats each and every response to the allegations set forth in Paragraphs “1” through “384” of the Complaint as if set forth at length herein.

386. Responding to Paragraph “386” of the Complaint, HOC admits that it designs, manufactures, markets and sells the Restoration® ADM/MDM™ X3® System. HOC denies the remaining allegations contained in Paragraph “386” of the Complaint.

387. HOC denies the allegations contained in Paragraph “387” of the Complaint.

388. HOC denies the allegations contained in Paragraph “388” of the Complaint.

389. HOC denies the allegations contained in Paragraph “389” of the Complaint.

390. HOC denies the allegations contained in Paragraph “390” of the Complaint.

391. HOC denies the allegations contained in Paragraph “391” of the Complaint.

392. HOC denies the allegations contained in Paragraph “392” of the Complaint.

393. HOC denies the allegations contained in Paragraph “393” of the Complaint.

394. HOC denies the allegations contained in Paragraph “394” of the Complaint.

395. HOC denies the allegations contained in Paragraph “395” of the Complaint.

**WHEREFORE**, HOC demands judgment in its favor and against Plaintiffs, dismissing the Eighth Cause of Action of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

**RESPONSE TO NINTH CAUSE OF ACTION AS AGAINST THE STRYKER & DEPUY  
– HUSBAND ANDRE ROUVIERE’S CLAIM FOR LOSS OF CONSORTIUM**

396. HOC repeats each and every response to the allegations set forth in Paragraphs “1” through “395” of the Complaint as if set forth at length herein.

397. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph “397” of the Complaint, and leaves Plaintiffs to their proofs.

398. HOC denies the allegations contained in Paragraph “398” of the Complaint.

399. HOC denies the allegations contained in Paragraph “399” of the Complaint.

**WHEREFORE**, HOC demands judgment in its favor and against Plaintiffs, dismissing the Ninth Cause of Action of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

### **AFFIRMATIVE DEFENSES**

#### **FIRST DEFENSE**

Plaintiffs fail to state a claim upon which relief may be granted.

#### **SECOND DEFENSE**

Plaintiffs’ claims are barred in whole or in part by the applicable statute of limitations.

#### **THIRD DEFENSE**

Any damages and/or injuries allegedly sustained by Plaintiffs were directly and proximately caused by independent, intervening and/or superseding causes which were unforeseeable to HOC.

#### **FOURTH DEFENSE**

Any recovery against HOC is barred by the application of the Learned Intermediary Doctrine.

#### **FIFTH DEFENSE**

Plaintiffs were comparatively negligent, and any recovery against HOC based on a finding of negligence (which HOC denies) is barred or must be reduced accordingly.

**SIXTH DEFENSE**

Plaintiffs are precluded from recovering against HOC pursuant to applicable law following Section 402A of the Restatement (Second) of Torts.

**SEVENTH DEFENSE**

Plaintiffs' recovery is barred under Section 6(c) of the Restatement of Torts (Third).

**EIGHTH DEFENSE**

Any and all losses or claims allegedly sustained by Plaintiffs are the result of acts and/or omissions of persons over whom HOC does not, or did not, have any direction or control, and for whose actions or omissions HOC is not liable.

**NINTH DEFENSE**

Any recovery by Plaintiffs will be reduced by past and/or future collateral source payments.

**TENTH DEFENSE**

Any recovery by Plaintiffs will be limited by Article 16 of the New York Civil Practice Law and Rules to the extent applicable.

**ELEVENTH DEFENSE**

The HOC and DePuy device components that are the subject of the Complaint are not compatible for use together, as set forth in the applicable product literature.

**TWELFTH DEFENSE**

HOC complied in all respects with the FDA and the regulatory process as set forth in the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act.

### **THIRTEENTH DEFENSE**

The imposition of punitive damages against HOC would violate HOC's rights under the Due Process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, the Excessive Fines clause in the Eighth Amendment to the Constitution of the United States, the Double Jeopardy clause in the Fifth Amendment to the Constitution of the United States, the equal protection clause of the Fourteenth Amendment to the Constitution of the United States, and the Sixth Amendment to the Constitution of the United States, in several regards, including but not limited to the following:

- a. imposition of punitive damages by a jury which is inadequately instructed regarding the rationale behind punitive damages, the standards/criteria governing such an award of damages, and/or the limits of such damages;
- b. imposition of punitive damages where applicable law is impermissibly vague, imprecise, or inconsistent;
- c. imposition of punitive damages that employs a burden of proof that is less than clear and convincing evidence;
- d. imposition of punitive damages without bifurcating the trial and trying all punitive damages issues separately, only if and after a finding on the merits of the liability of Defendant;
- e. imposition of punitive damages without any predetermined limit on any such award;
- f. imposition of punitive damages which allows multiple punishment for the same alleged act(s) or omission(s); and
- g. imposition of punitive damages without consistent appellate standards of review of such an award.



**FOURTEENTH DEFENSE**

HOC reserves the right to assert all defenses, whether affirmative or otherwise, about which it presently lacks sufficient information but which may become available to it during the course of this litigation.

**WHEREFORE**, Howmedica Osteonics Corp. demands judgment in its favor and against Plaintiffs, dismissing Plaintiffs' Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

Dated: January 7, 2019  
New York, New York

**GIBBONS P.C.**  
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New York, New York 10019-3701  
(212) 613-2000  
*Attorneys for Defendant*  
*Howmedica Osteonics Corp.*

By: s/ Paul E. Asfendis  
Kim M. Catullo  
Paul E. Asfendis

**CERTIFICATE OF SERVICE**

I hereby certify that on January 7, 2019, I caused Defendant Howmedica Osteonics Corp.'s Answer to Amended Complaint and Affirmative Defenses to be served upon the pro se Plaintiffs via overnight delivery to:

Jodi and Andre Rouviere  
4070 Laguna Street  
Coral Gables, Florida 33146

s/ Paul E. Asfendis

Paul Asfendis